



#23

PATENT
Docket No.: 201487/1030 (SEN-002PCT-US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Karube et al.)	Examiner:
)	B. Loeb
Serial No.	:	CPA of 09/623,970)	
)	
Cnfrm. No.	:	1866)	Art Unit:
)	1636
Filed	:	March 12, 1999)	
)	
For	:	SITE-SPECIFIC CELL PERFORATION)	
		TECHNIQUE)	

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REQUEST FOR RECONSIDERATION

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the May 7, 2002, office action and the December 4, 2002, advisory action, applicants respectfully request reconsideration of the above application.

The rejection of claims 1 and 22-24 under 35 U.S.C. § 112 (1st para.) for lack of written description is respectfully traversed.

It is the position of the U.S. Patent and Trademark Office ("PTO") that the specification fails to provide an adequate written description of combinations of membrane-disrupting reagents and stimuli other than the one combination of photosensitizing compounds plus light stimulation. The PTO also asserts that the single disclosed species is not representative of the number of species encompassed by the genus. Applicant respectfully disagrees.

First, applicants submit that the disclosure of the present invention is more than sufficient to demonstrate that they had possession of the claimed invention. The "membrane-disrupting reagent" of the claimed invention is defined as a reagent that induces a membrane-denaturing reaction when the membrane is exposed to a stimulus, and includes, as

described on page 9, lines 16-27, enzymes, antibody molecules, membrane bound proteins, glycoproteins, lipids, photosensitizers, oxidants, reductants, explosive compounds, magnetic particulates, metal particles, etc. In addition, the “stimulus” of the claimed invention is restricted to those that induce the membrane-denaturing reaction of the membrane-disrupting reagent selected and includes electromagnetic waves, particle rays, heat, cooling, electricity, magnetism, oscillations, physical contact, chemical substances, cells, and viruses, as described on page 9, lines 6-15. Moreover, page 4, line 35 – page 7, line 18, page 10, lines 7-22 and 31-35, page 12, lines 15-24, and page 25, line 19- page 33, line 24 of the present application disclose using a combination of a photosensitizer and light to disrupt a membrane temporarily and partially only at the contact site.

Furthermore, as indicated in the accompanying Declaration of Takashi Saitoh Under 37 C.F.R. § 1.132 (“Saitoh Declaration”), site-specific regulated membrane penetration can also be performed with other combinations of membrane-disrupting reagents and stimuli besides the photosensitizer-light combination. Thus, a cell can be contacted with a capillary containing a sonosensitizer as the membrane-disrupting reagent and stimulated by sonication with a piezoelectric immersion transducer (Saitoh Declaration ¶¶ 3-7). Out of a total of 24 cells tested, the number of cells that were penetrated increased from 0 cell to 7 or 8 cells (excluding the cells that were penetrated due to mechanical shock) by applying a sonosensitizer, showing that site-specific regulated membrane penetration can be performed with a combination of a sonosensitizer and sonication (Saitoh Declaration ¶ 8). Therefore, applicants submit that the presently claimed genus of using a combination of membrane-disrupting reagent and a stimulus is adequately represented by the species taught and described in the present application and the accompanying Saitoh Declaration.

Accordingly, the rejection of claims 1 and 22-24 under 35 U.S.C. § 112 (1st para.) for lack of written description is improper and should be withdrawn.

In view of all the foregoing, it is submitted that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: July 23, 2003

Alice Y. Choi
Alice Y. Choi
Registration No. 45,758

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603
Telephone: (585) 263-1508
Facsimile: (585) 263-1600

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450, on the date below.	
<u>July 23, 2003</u> Date	<u>Ruth R. Smith</u> Ruth R. Smith